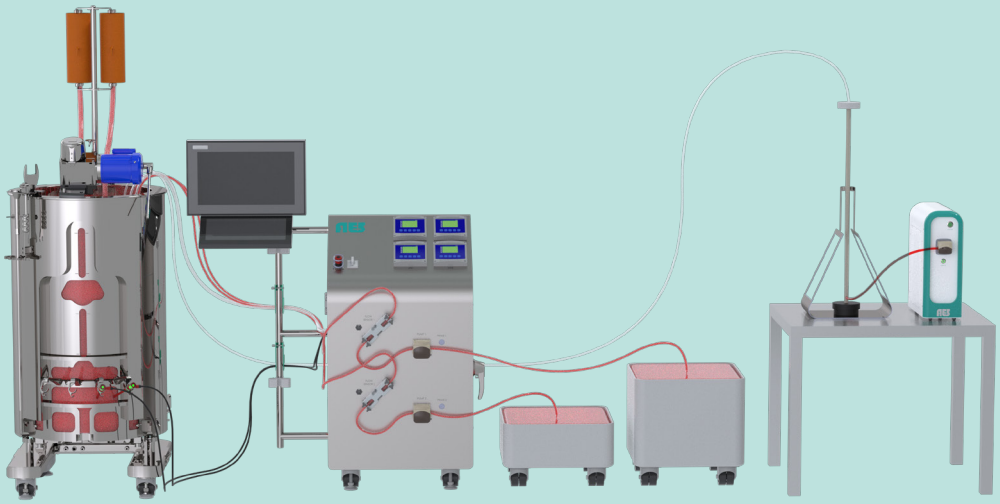
Automated Engineering Services, Inc.

TECHNICAL BROCHURE



Adaptive Single-Use Bioreactor Control System

PERFUSION

PRODUCT SUMMARY

Elevate your bioprocessing capabilities with AES's Adaptive Single-Use Bioreactor (SUB) Control System with Perfusion, a revolutionary design for unparalleled flexibility and performance. Our SUB Control System offers seamless integration with Rockwell controls or can accommodate the client's preferred control system. Thanks to configurable components with versatile operating ranges, the operator can tailor the hardware options to meet your specific process requirements. Elevate reliability with the addition of redundant condition monitoring, guaranteeing uninterrupted perfusion control. Operate the system manually, or utilize semi-automated sequences to maximize flexibility in cell expansion and growth processes. This empowers users with smooth operational freedom.

APPLICATIONS:

Unlock the potential of bioprocessing across diverse applications with AES's Adaptive SUB Control System with Perfusion. Tailored to meet the evolving needs of the biopharmaceutical industry, we offer versatile solutions for a range of applications, ensuring optimal outcomes and efficiency.

- Monoclonal Antibody Production (mAb)
- Cell Culture & Expansion
- Gene & Cell Therapy
- Stem Cell Research

BENEFITS OF THE ADAPTIVE SUB CONTROL SYSTEM WITH PERFUSION:

- Enhances efficiency through continuous nutrient supply and waste removal.
- Seamlessly integrates interfaces for precise process control and insights.
- Guarantees maximum manufacturing flexibility with perfusion.
- Minimizes capital investment with optimized perfusion technology.
- Acceletates facility start-up for quicker time to market.

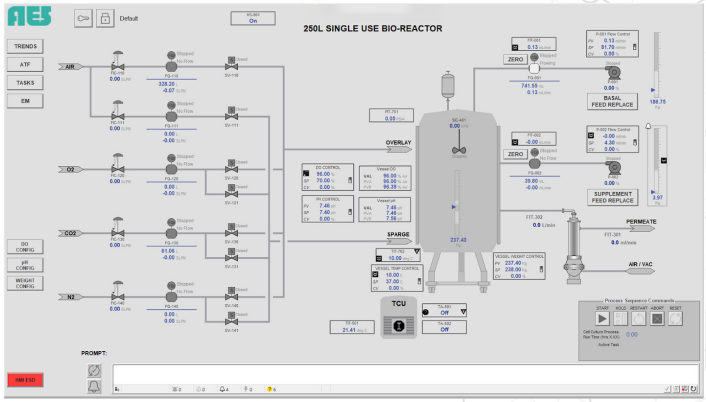
DESIGNED FOR A REGULATED ENVIRONMENT:
This SUB Control System with Perfusion is designed to meet the rigorous demands and standards required in a regulated environment. The SUB Control System is designed with GMP and 21 CFR Part 11 compliance in mind.

SYSTEM OVERVIEW

The Adaptive SUB Control System with Perfusion is a holistic solution that provides unparalleled control and adaptability in cell growth and expansion processes. Comprising key components such as the Bioreactor Control Panel and an auxiliary Temperature Control Unit (TCU), this system ensures precision, flexibility, and optimal performance across various applications. The Bioreactor Control Panel is designed to seamlessly interface with a variety Single-Use Bioreactor vessel sizes, providing a versatile and customizable solution tailored to the specific requirements of your processes.

BIOREACTOR CONTROL PANEL:
Our Bioreactor Control Panel integrates cutting-edge features to streamline your bioreactor management. With an intuitive Human-Machine Interface (HMI) displayed on a 19.5in screen, operators can effortlessly interact and monitor the bioreactor system. From liquid management to gas control and real-time weight measurement, our control panel ensures seamless operation and optimal cell expansion and growth conditions.

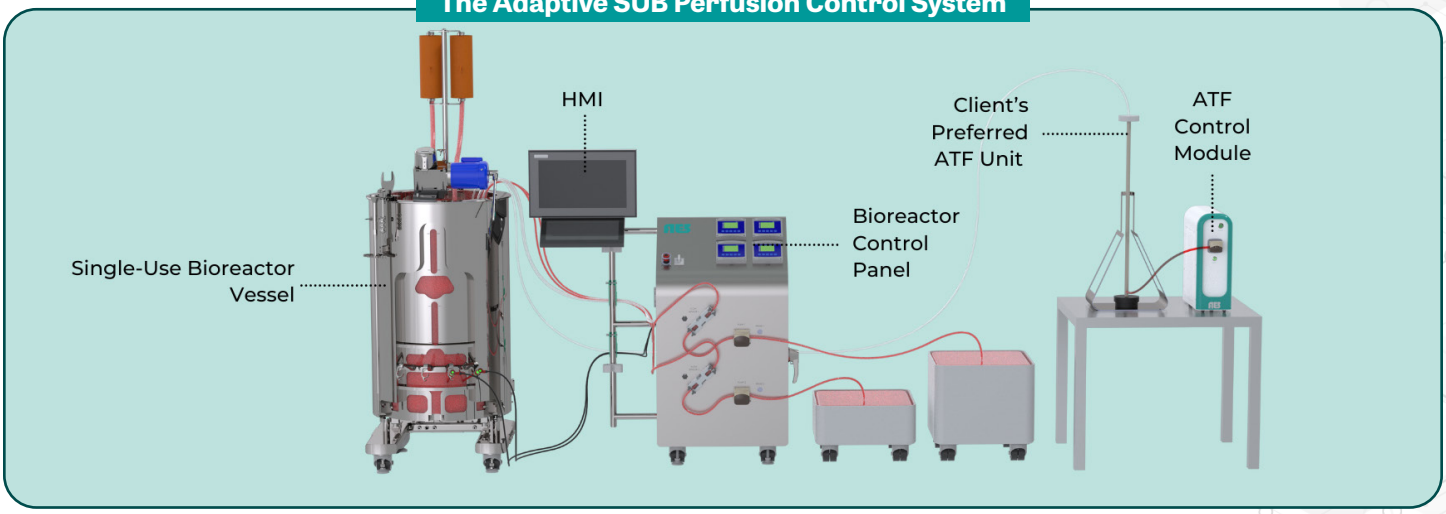
Automation & Control:
The Bioreactor Control Panel's Human-Machine Interface (HMI) is the intuitive control center at the core of user interaction. Crafted for simplicity and efficiency, it empowers operators to interact with and monitor the bioreactor effortlessly, facilitating smooth navigation through settings, real-time data access, and precise command execution. The SUB Control Panel orchestrates the comprehensive operation of the system, enabling users to tailor cell expansion and growth processes with precision. Whether opting for manual control or semi-automated sequences, the system ensures flexibility to meet specific process requirements. It seamlessly integrates with Rockwell software, providing an intuitive and user-friendly interface.Alternatively, users can choose their preferred control system, allowing for a customized and effortless experience managing the SUB Control Panel.



The featured overview screen exhibits sample numbers exclusively and is subject to variation based upon the client's operational process workflow.

Liquid Management:
The Liquid Control subsystem within the SUB Control Panel ensures precise liquid handling through two peristaltic flip-top pump heads, delivering dynamic pumping capabilities adaptable to diverse processes. This setup is complemented by two single-use flow meters integrated with transmitters, ensuring accurate liquid measurement with impressive precision within a specified flow range.

The Adaptive SUB Perfusion Control System

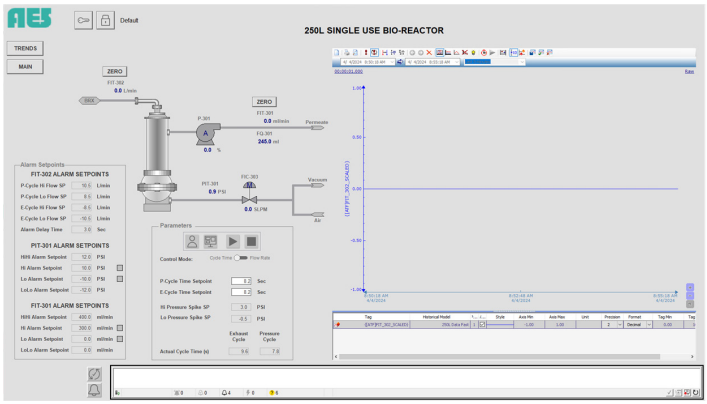


Gas Control:
The SUB Control System is pivotal in overseeing the precise management of gases essential for cell expansion and growth. Five Mass Flow Controllers (MFCs) accurately

regulate Clean Compressed Air (CCA), O_2, CO_2, and N_2 flow rates. Gas flow to Bioreactor HEADSPACE or SPARGE is managed through a valve manifold, with each MFC having independent shutoff valves. The system facilitates the integration of additional gases for overlay and sparging strategies. This advanced Gas Control mechanism ensures an environment conducive to optimal cell growth, contributing to the success of your bioprocessing endeavors.

Weight Measurement:
The SUB Control System features Integrated Load Cells, ensuring real-time precision for bioreactor content monitoring. This crucial feature maintains balance throughout the cell expansion and growth process.
In line with our commitment to adaptability, optional features include media scales that can cater to diverse bioprocessing needs. The maximum capacity and readability of the media scales depend on each client's

Alternative Tangential Flow (ATF) Control:
A key feature of the Perfusion SUB System is its incorporation of ATF control, marking a significant advancement in bioprocessing capabilities. The ATF Control utilizes a bi-directional MFC that harnesses compressed air and vacuum utilities to power the diaphragm pump. This MFC inflates and delflates the diagphragm pump optimizing filtration by pulling media over the filter during deflation and pushing it back into the reactor upon inflation. In addition, a bidirectional capable pump is used to meter the permeate flow through the ATF. This dynamic control mechanism ensures optimal filtration, resource efficiency,and a seamless bioprocessing experience.



The featured ATF screen exhibits sample numbers exclusively and is subject to variation based upon the client's operational process workflow.

TEMPERATURE CONTROL UNIT:
The SUB Control System interfaces with the auxiliary TCU to maintain precise, consistent temperature ranges essential for temperature-sensitive cell expansion and growth processes. The TCU is critical in supporting bioprocessing capabilities with remarkable accuracy and a broad operating range. Its cutting-edge design embodies adaptability and reliability, offering a comprehensive solution to achieve optimal results in various applications.

VESSEL & BAG SELECTION:
At AES, we understand that each client's bioprocessing needs are unique. While our system is optimized for the Thermo Fisher HyPerformal™ line, we pride ourselves on flexibility. Our bioreactor system can be designed to accommodate any preferred vessel that aligns with the specific process demands. Whether it's a different vessel size, model, or brand, our commitment is to provide a tailored solution that meets the distinct requirements of your processes. This adaptability ensures that the AES SUB System is not only optimized for current technologies but is also future-proof, ready to evolve with the advancements in the bioprocessing industry.

DATA AND COMMUNICATION:
The AES Adaptive SUB Control System is an innovative lab equipment that provides precise data and control functions during cell expansion and growth. The user-friendly interface displays real-time and historical data and can meet the specific needs of each experiment. Additionally, the platform can include advanced features such as remote monitoring and control, data logging, and alarm notifications, allowing for efficient and reliable operation. This SUB Contol System excels in data and communication, seamlessly integrating with protocols for efficient information exchange. Using cutting-edge technology, it enables real-time data transfer, enhancing monitoring and control. Whether connecting with external devices or establishing internal bioreactor connectivity, the control panel ensures a robust network, boosting overall efficiency in bioprocessing. Trust in its enhanced features to propel your capabilities to new heights.

TECHNICAL SPECIFICATIONS

Equipment Specifications				
Enclosure Footprint (H x W x D)	17 in x 26 in x 61 in 43.18 cm x 66.04 cm x 154.94 cm			
Power Requirements	120 - 230 VAC, 50/60 Hz, 1200 Watts			
Vessel Volume	50L	100L	250L	500L
Vessel Compatibility	Thermo Fisher Hyperforma™ or Preffered Vessel			
Mobility	Mounted on (4) Casters			

SUB Equipment & Specifications		
Process Analytics		
Agitation	50L & 100L	30 – 200 RPM
	250L & 500L	30 – 150 RPM
Weight Measurement	Integrated Load Cells	
Temperature Sensor	(1) RTD Sensor	
Temperature Range	-5 to 250°C, ±0.1°C	
Pressure Sensor	(1) Single-Use Probe	
Pressure Range	0 – 2 psi, ±0.012psi	
pH Sensor	(1) Single-Use Probe	
pH Range	3 – 10 pH, ±0.10 pH	
DO Sensor	(1) Single-Use Probe	
DO Range	0 – 250% air,< 2.5%	
Vent Filter Heater Control	Local & Remote	
Vent Heater Range	40 to 100°C, ±5°C	
Redundant pH, DO, & Vent Filter can be configured		
Liquid Control		
Onboard Pumps	(2) pumps with Bi-Directional Stepper Motors	
Pump Head Type	Peristaltic, Flip-Top Pump Heads	
Pump Speed Range	0.2 – 200 RPM or 0.2 - 300 RPM*	
Flow Meters	(2) Single-Use Flow Meters	
Flow Meter Range	6 – 800mL/min ±1%	
Flow Meter Communication Protocol	Analog or Modbus*	
Gas Control		
MFC Quantity & Gas Type	(5) MFCs: CCA (Clean Compressed Air), O_2, CO_2, and N_2	
Instrument Range	0.003 – 50 SLPM (operating ranges and flowrate units are user-configurable)	
Communication Protocol	Modbus RS485 or Ethernet/IP*	
Perfusion		
ATF Specifications		
ATF Compatibility	Repligen XCell® ATF	
Effective Surface Area	50L, 100L& 250L	2.5 m^2
	250L & 500L	11 m^2
Volume Exchanged	50L, 100L & 250L	1.3 L
	250L & 500L	6.0 L
Vacuum Source	Remote Vacuum Pump	
Pressure Control		
Pressure Sensor	(1) Sensor	
Pressure Range	-1 to 1 bar	
Liquid Control		
On-Board Pumps	(1) Pump with 24VDC Bi-Directional Stepper Motor	
Pump Head Type	Peristaltic, Flip-Top	
Pump Speed Range	0.2 - 200 RPM or 0.2 - 300 RPM*	
Tubing Compatibility	L/S -13, -14, -16, - 25, -17, -18	

* Optional instrumentation, if configured

Tubing Compatibility	L/S -13, -14, -16, - 25, -17, -18	
Permeate Flow Meter	(1) Clamp-on Flow Meter	
Permeate Flow Meter Range	0 – 8000 mL/min ±16 mL/min	
Gas Control		
MFC Quantity & Gas Type	(1) Bi-directional MFC: CCA (Clean Compressed Air), Vacuum Source	
Instrument Range	-20 to +20 SLPM	
Communication Protocol	Modbus RS485 or Ethernet/IP*	
External Equipement		
Weight Measurement		
Media Scale	50L	300kg, 10g readability
	100L	600kg, 100g readability
	250L	1500kg, 200g readability
	500L	3000kg, 500g readability
Temperature Control Unit		
Tempeature Range	5°C to 40°C, ±0.1°C	
Automation & Control Software		
Standard Offering	AES Library Rockwell™	
Deluxe Offering	DeltaV + Process Sequence Model functionality, DeltaV based Perfusion Control	
Optional Features	DeltaV configuration of auxiliary I/O signals or custom ancillary equipment/ instrumentation	
HMI		
Display Size	19.5in | 49.53cm	
Keyboard	Yes	
Enclosure Rating	IP65/IP66	

* Optional instrumentation, if configured